

### **REMARKS**

Applicants hereby request further consideration of the application in view of the amendments above and the comments that follow.

Claims 22-28 have been cancelled without prejudice as directed to a non-elected invention group, and Applicants reserve the right to pursue these claims in a future divisional patent application.

In the event that the Examiner does not deem the arguments and amendments set forth herein sufficient to place the application in condition for allowance, Applicants respectfully request that the Examiner contact the undersigned to conduct a telephonic interview.

### **Interview Summary**

Applicants provide the present Interview Summary to respond to the Interview Summary mailed October 12, 2007, of an interview with Applicants' representative, David D. Beatty on October 5, 2007. During the interview, Applicants argued that Gordon does not provide an adequately sealed vessel. Applicants otherwise concur in the Interview Summary provided by the Examiner as accurately reflecting the interview.

### **Status of the Claims**

Claims 1-5, 7, 9, 11, 12, 14, 15, 17, 18 and 21 stand rejected under Section 103(a) as being unpatentable over U.S. Patent No. 4,215,198 to Gordon (Gordon) in view of U.S. Patent No. 5,094,955 to Calandra et al. (Calandra). Claims 11-13 and 20 stand rejected under Section 103(a) as being unpatentable over Gordon in view of Calandra and further in view of U.S. Patent No. 4,643,197 to Greene et al. (Greene).

### **The Rejections under Section 103**

Independent Claims 1, 14 and 21 stand rejected under Section 103 over Gordon in view of Calandra. The Final Action contends that it would have been obvious to one of ordinary skill in the art to employ a sensor as taught by Calandra in the Gordon device and,

furthermore, that it would have been obvious to position the sensor on the cap (15, 115) of the device of Gordon. Applicants respectfully disagree.

The device of Gordon is constructed in a manner that would make it unsuitable for modification in the manner suggested by the Final Action and would prevent the ordinarily skilled artisan from contemplating such modification. While Calandra discloses that the sensor thereof may be placed in proximity to or form a part of a cap, the caps (*e.g.*, the stopper 3 in **Figure 5** and the stopper 4 in **Figure 6**) as illustrated appear to be secure stoppers constructed to maintain a reliable, gas-tight seal with the container. By contrast, Gordon discloses a hinged cap 15 (or 115) that, as illustrated and described, does not appear capable of providing a robust hermetic seal with the container 11. In particular, the seal between the cap 15 and the container 11 does not appear to be sufficient to adequately withstand the forces associated with the processes as described in Calandra. For example, it does not appear that the seal between the cap 15 and the container 11 would provide an adequate seal when subjected to the stresses attendant to agitation of the specimen, which may be required for optimal growth of microorganisms present in the specimen. The gaseous byproducts generated by a specimen typically generate pressure in the chamber, presenting a risk that such gaseous byproducts would leak or escape from the container 11 of Gordon through the interface with the cap 15 about the inlet port 13, and may even dislodge the cap 15 from the container 11. Such leakage may present several problems. The escaped gas may contaminate the surrounding environment. In particular, the escaped gas may include aerosols containing microorganisms that deposit on an adjacent operator, incubator or the like. Also, the loss of the generated gaseous byproducts may diminish the accuracy, consistency and/or speed of detection by removing the detectable substance (*e.g.*, CO<sub>2</sub>) from the container 11. Breach of the seal about the cap 15 may also risk contamination of the sample in the container 11. Therefore, the ordinarily skilled artisan would not consider incorporating the sensor systems of Calandra into the device of Gordon as suggested by the Final Action.

Responsive to the foregoing arguments (which were presented in response to the Final Action), the Advisory Action states:

In response, Applicants' comments are not found to be persuasive for the following reasons. Applicants' comments are not commensurate in scope with the instant claim language. That is, the independent claims do not require a sealed vessel. Also, the reference of Gordon states that the cap "tightly closes" the vessel (See column 5, line 27). Additionally, the Examiner is of the position that providing a gas-tight seal, if not inherent in the reference of Gordon, is within the level of skill in the art during culturing of the sample to prevent contamination of the sample. This is supported by the disclosure of Calandra et al. which discloses the use of a sealed vessel with the sensor device even when the sensor device is not in direct contact with liquid culturing medium. Finally, note arguments of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Regarding the first, third and fourth reasons, Applicants submit that regardless of whether Claims 1, 14 and 21 require a sealed vessel or Calandra provides a well-sealed vessel, Gordon does not obviously lend itself to modification in the manner necessary or proposed to present an apparatus corresponding to the claimed invention. Regarding the second reason, although Gordon discloses that the cap 15 is "adapted to tightly close the inlet port 13", "tightly close" is an ambiguous qualifier and it nonetheless does not appear that the cap arrangement of Gordon is capable of providing a robust hermetic seal between the cap 15 and the container 11.

In view of the foregoing, Applicants respectfully submit that the inventions of Claims 1, 14 and 21 are patentable over the cited art. Claims 2-5, 7, 9, 11-13, 15, 17, 18, 20 and 29-39 each depend from one of Claims 1, 14 and 21 and are therefore allowable over the cited art for at least these reasons. At least certain of the dependent claims are further patentably distinguishable from the cited art.

New Claims 29, 39 and 40 depend from Claims 1, 14 and 21, respectively, and each further recite:

wherein said device has an operative testing orientation and, when said device is in the operative testing orientation, said sensor resides at a lower end of said chamber and below said filter.

For example, as illustrated in **Figures 6 and 7** of Applicants' specification, the device **100** has an operative testing orientation wherein the sensor **120** is located below the filter **130**. Such positioning may ensure that the culturing medium adequately contacts the sensor **120**, which may be a sensor of the type that requires fluid contact to properly react to and indicate the presence of microorganisms or their growth byproducts. Such placement may be particularly valuable when the device is agitated to promote microorganism growth as discussed above. The device of Gordon does not have an operative testing orientation wherein the cap **15** resides at a lower end of the container **11** and below the filter **23**. In view of the leakage risks discussed above, the ordinarily skilled artisan would have regarded inversion of the container **11** of Gordon to be impractical and unsafe.

New Claim 30 depends from Claim 29 and further recites:

30. The device of Claim 29 wherein said end wall is a fixed end wall of said container having a continuous closed surface.

New Claim 31 depends from Claim 30 and further recites:

31. The device of Claim 30 wherein said container is unitary and said inlet and said outlet are the only openings into said container communicating with said chamber.

New Claim 32 depends from Claim 31 and further recites:

32. The device of Claim 31 wherein, when said device is in the operative testing orientation, said inlet and said outlet are each located above said sensor.

Support for Claims 30-32 can be found in Applicants' specification at **Figures 1 and 2**, for example. An integrated filtration and detection device as recited in Claims 30-32 may provide certain distinct advantages. The claimed construction may provide a chamber for the specimen and culturing medium that is hermetically sealed, the hermetic seal being

sufficiently robust to withstand agitation (*e.g.*, shaking of the container) and high internal pressure (*e.g.*, from heating and/or microbial gas production) without breaching the hermetic seal. The claimed construction may permit the container of the device to be inverted to ensure effective and reliable liquid contact between the sensor and the culturing medium without jeopardizing the hermetic seal. The enablement of liquid contact between the culturing medium and the sensor and the ability to safely and reliably withstand agitation and heating may provide for particularly rapid and effective detection of microbial growth in a specimen. As such, integrated filtration and detection devices as recited in Claims 30-32 may be particularly well-suited for on-line or real-time sampling and testing for microbial growth. By contrast, the removable and replaceable cap 15 of Gordon is clearly not a fixed end wall of the container 11. Accordingly, Claims 30-32 are patentably distinguishable from the cited art for these additional reasons.

New Claims 33 and 34 depend from Claim 1 and are also further patentably distinguishable from the cited art for the reasons discussed above with regard to Claims 30 and 31.

New Claim 35 depends from Claim 1 and further recites:

35. The device of Claim 1 wherein said container includes:  
a container body having an end opening opposite said end  
wall on which said sensor is mounted; and  
an end cap secured over and sealing said end opening.  
wherein said inlet and said outlet are formed in said end  
cap.

Applicants respectfully submit that the inventions of Claim 35 as well as Claim 13 would not have been obvious in view of Gordon, Calandra and Greene as applied by the Final Action to Claim 13. It is not apparent how one of ordinary skill in the art might incorporate both the inlet and the outlet into either the cap 15 or the ball 27 of Gordon. Presumably, any such modification would fundamentally alter the operation and functionality of the Gordon device.

New Claim 36 depends from Claim 1 and further recites:

36. The device of Claim 1 including a liquid culturing medium  
disposed in said chamber, wherein:

said sensor resides at a lower end of said chamber and below said filter; and  
said liquid culturing medium is disposed in said lower end of said chamber and contacts said sensor in said lower end of said chamber.

Claim 36 thus recites the further component of a liquid culturing medium as well as the structural relationships between the chamber, the end wall, the sensor, the filter and the liquid culturing medium. For at least the reasons discussed above with regard to Claim 29, it would not have been obvious to modify the device of Gordon such that the cap **15**, the proposed sensor and the liquid culturing medium are located in or at a lower end of the chamber below the filter **23**.

New Claim 37 depends from Claim 36 and further recites:

37. The device of Claim 36 wherein:  
said end wall is a fixed end wall of said container having a continuous closed surface; and  
said inlet and said outlet are each located above said sensor.

Claim 37 thus more particularly sets forth the structure of the container and its end wall as well as the structural relationships between the sensor and the inlet and outlet. Accordingly, Claim 37 is also patentably distinguishable from the cited art for the reasons discussed above with regard to Claims 30 and 32.

New Claim 38 depends from Claim 36 and further recites:

38. The device of Claim 36 wherein said chamber is fully sealed.

Claim 38 therefore addresses the concern set forth in the Advisory Action that the claims do not require a "sealed vessel".

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**CONCLUSION**

Applicants respectfully submit that this application is now in condition for allowance, which action is requested. Should the Examiner have any matters outstanding of resolution, he is encouraged to telephone the undersigned at 919-854-1400 for expeditious handling.

Respectfully submitted,



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**CERTIFICATION OF TRANSMISSION**

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the U.S. Patent and Trademark Office on October 24, 2007.



Kirsten S. Carlos